



ANDA 208811

AMENDMENT ACKNOWLEDGEMENT

Priority

Mylan Institutional LLC
781 Chestnut Ridge Road
P.O. 4310
Morgantown, WV 26504-4310
Attention: Martina O'Sullivan
Head of Global Regulatory Affairs Injectables

Dear Madam:

This is in reference to your amendment received on [REDACTED] submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per syringe.

This amendment is subject to the provisions of the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II). FDA has made an initial determination that this is a [REDACTED] amendment and it meets the criteria for a priority review per the Center for Drug Evaluation and Research's Manual of Policies and Procedures 5240.3, *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*. The GDUFA goal date for review of this priority [REDACTED] amendment is [REDACTED].

If you have any questions, contact David Trang, Regulatory Project Manager, at (301) 796 - 8667.

Sincerely,

{See appended electronic signature page}

David Trang, Pharm.D., MBA
Regulatory Project Manager
Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



David
Trang

Digitally signed by David Trang

Date: [REDACTED] 08:14:47AM

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